

SENATE BILL 750

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CF 2lr2516

By: **Senator Middleton**

Introduced and read first time: February 3, 2012

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Maryland Health Care Commission – Cardiac Surgery and Percutaneous**
3 **Coronary Intervention Services**

4 FOR the purpose of requiring, with a certain exception, a certificate of need for the
5 establishment of percutaneous coronary intervention (PCI) services; requiring,
6 beginning on a certain date, an acute general hospital to have a certificate of
7 conformance before the hospital may establish primary PCI services or
8 nonprimary PCI services; prohibiting the Maryland Health Care Commission
9 from issuing a certificate of conformance unless the Commission finds that the
10 proposed primary PCI services or proposed nonprimary PCI services meet
11 certain standards; providing that a certificate of conformance is not required,
12 notwithstanding certain provisions of this Act, for an acute general hospital to
13 establish primary PCI services under certain circumstances; requiring an acute
14 care hospital that provides cardiac surgery or PCI services under certain
15 authorization to obtain and maintain a certificate of ongoing performance to
16 continue to provide cardiac surgery services, primary PCI services, or
17 nonprimary PCI services; requiring an acute general hospital that is providing
18 nonprimary PCI services under a research waiver issued by the Commission to
19 obtain a certificate of conformance for its nonprimary PCI services before it may
20 obtain a certificate of ongoing performance to provide the nonprimary PCI
21 services; requiring the Commission to adopt certain regulations; requiring the
22 regulations to include certain items; establishing certain parameters for the
23 process established by the Commission for issuing a certificate of conformance;
24 authorizing a certain hospital, notwithstanding certain provisions of this Act, to
25 provide nonprimary PCI services until the Commission takes certain actions;
26 defining certain terms; and generally relating to the regulation of cardiac
27 surgery and percutaneous coronary intervention services by the Maryland
28 Health Care Commission.

29 BY repealing and reenacting, without amendments,
30 Article – Health – General

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 Section 19–120(j)(1)
2 Annotated Code of Maryland
3 (2009 Replacement Volume and 2011 Supplement)

4 BY repealing and reenacting, with amendments,
5 Article – Health – General
6 Section 19–120(j)(2)
7 Annotated Code of Maryland
8 (2009 Replacement Volume and 2011 Supplement)

9 BY adding to
10 Article – Health – General
11 Section 19–120.1
12 Annotated Code of Maryland
13 (2009 Replacement Volume and 2011 Supplement)

14 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
15 MARYLAND, That the Laws of Maryland read as follows:

16 **Article – Health – General**

17 19–120.

18 (j) (1) A certificate of need is required before the type or scope of any
19 health care service is changed if the health care service is offered:

20 (i) By a health care facility;

21 (ii) In space that is leased from a health care facility; or

22 (iii) In space that is on land leased from a health care facility.

23 (2) This subsection does not apply if:

24 (i) The Commission adopts limits for changes in health care
25 services and the proposed change would not exceed those limits;

26 (ii) The proposed change and the annual operating revenue that
27 would result from the addition is entirely associated with the use of medical
28 equipment;

29 (iii) The proposed change would establish, increase, or decrease
30 a health care service and the change would not result in the:

31 1. Establishment of a new medical service or elimination
32 of an existing medical service;

1 **(3) “CERTIFICATE OF ONGOING PERFORMANCE” MEANS AN**
2 **APPROVAL ISSUED BY THE COMMISSION THAT THE CARDIAC SURGERY**
3 **SERVICES, PRIMARY PCI SERVICES, OR NONPRIMARY PCI SERVICES PROVIDED**
4 **BY AN ACUTE GENERAL HOSPITAL MEET STANDARDS EVIDENCING CONTINUED**
5 **QUALITY.**

6 **(4) (I) “NONPRIMARY PCI” MEANS PCI CAPABLE OF**
7 **RELIEVING CORONARY-VESSEL NARROWING ASSOCIATED WITH CORONARY**
8 **ARTERY DISEASE UNRELATED TO ST-SEGMENT-ELEVATION MYOCARDIAL**
9 **INFARCTION.**

10 **(II) “NONPRIMARY PCI” INCLUDES ELECTIVE PCI.**

11 **(5) “PCI” MEANS PERCUTANEOUS CORONARY INTERVENTION.**

12 **(6) (I) “PERCUTANEOUS CORONARY INTERVENTION” MEANS A**
13 **PROCEDURE IN WHICH A CATHETER IS INSERTED INTO A BLOOD VESSEL AND**
14 **GUIDED TO THE SITE OF THE NARROWING OF A CORONARY ARTERY TO RELIEVE**
15 **CORONARY NARROWING.**

16 **(II) “PERCUTANEOUS CORONARY INTERVENTION”**
17 **INCLUDES A VARIETY OF CATHETER-BASED TECHNIQUES, INCLUDING BALLOON**
18 **ANGIOPLASTY.**

19 **(7) “PRIMARY PCI” MEANS PCI CAPABLE OF RELIEVING**
20 **CORONARY VESSEL NARROWING ASSOCIATED WITH ST-SEGMENT-ELEVATION**
21 **MYOCARDIAL INFARCTION.**

22 **(B) (1) BEGINNING JULY 1, 2012, BEFORE AN ACUTE GENERAL**
23 **HOSPITAL MAY ESTABLISH PRIMARY PCI SERVICES OR NONPRIMARY PCI**
24 **SERVICES, THE HOSPITAL SHALL OBTAIN A CERTIFICATE OF CONFORMANCE**
25 **FROM THE COMMISSION.**

26 **(2) THE COMMISSION MAY NOT ISSUE A CERTIFICATE OF**
27 **CONFORMANCE UNLESS THE COMMISSION FINDS THAT THE PROPOSED**
28 **PRIMARY PCI SERVICES OR PROPOSED NONPRIMARY PCI SERVICES:**

29 **(I) ARE CONSISTENT WITH THE STATE HEALTH PLAN FOR**
30 **FACILITIES AND SERVICES;**

31 **(II) WILL RESULT IN THE DELIVERY OF MORE EFFICIENT**
32 **AND EFFECTIVE HEALTH CARE SERVICES; AND**

1 **(III) ARE IN THE PUBLIC INTEREST.**

2 **(C) NOTWITHSTANDING SUBSECTION (B) OF THIS SECTION, A**
3 **CERTIFICATE OF CONFORMANCE IS NOT REQUIRED FOR AN ACUTE GENERAL**
4 **HOSPITAL TO ESTABLISH PRIMARY PCI SERVICES IF:**

5 **(1) THE ACUTE GENERAL HOSPITAL WAS PROVIDING PRIMARY**
6 **PCI SERVICES ON JANUARY 1, 2012; AND**

7 **(2) THE COMMISSION DETERMINES THAT THE PRIMARY PCI**
8 **SERVICES ARE CONSISTENT WITH THE STATE HEALTH PLAN FOR FACILITIES**
9 **AND SERVICES.**

10 **(D) (1) THIS SUBSECTION APPLIES TO AN ACUTE CARE HOSPITAL**
11 **THAT PROVIDES CARDIAC SURGERY OR PCI SERVICES UNDER:**

12 **(I) A CERTIFICATE OF NEED ISSUED UNDER § 19-120 OF**
13 **THIS SUBTITLE;**

14 **(II) A CERTIFICATE OF CONFORMANCE ISSUED UNDER THIS**
15 **SECTION; OR**

16 **(III) AN EXCEPTION FROM THE CERTIFICATE OF**
17 **CONFORMANCE REQUIREMENTS UNDER SUBSECTION (C) OF THIS SECTION.**

18 **(2) AN ACUTE GENERAL HOSPITAL SHALL OBTAIN AND MAINTAIN**
19 **A CERTIFICATE OF ONGOING PERFORMANCE TO CONTINUE TO PROVIDE:**

20 **(I) CARDIAC SURGERY SERVICES;**

21 **(II) PRIMARY PCI SERVICES; OR**

22 **(III) NONPRIMARY PCI SERVICES.**

23 **(E) AN ACUTE GENERAL HOSPITAL THAT IS PROVIDING NONPRIMARY**
24 **PCI SERVICES UNDER A RESEARCH WAIVER ISSUED BY THE COMMISSION**
25 **SHALL OBTAIN A CERTIFICATE OF CONFORMANCE FOR ITS NONPRIMARY PCI**
26 **SERVICES BEFORE THE ACUTE GENERAL HOSPITAL MAY OBTAIN A CERTIFICATE**
27 **OF ONGOING PERFORMANCE TO PROVIDE THE NONPRIMARY PCI SERVICES.**

1 **(F) (1) THE COMMISSION SHALL ADOPT REGULATIONS THROUGH AN**
2 **UPDATE TO THE STATE HEALTH PLAN FOR FACILITIES AND SERVICES TO**
3 **IMPLEMENT THIS SECTION.**

4 **(2) THE REGULATIONS SHALL:**

5 **(I) ADDRESS QUALITY, ACCESS, AND COST;**

6 **(II) ESTABLISH A PROCESS AND MINIMUM STANDARDS FOR**
7 **OBTAINING A CERTIFICATE OF CONFORMANCE;**

8 **(III) ESTABLISH A PROCESS AND MINIMUM STANDARDS FOR**
9 **OBTAINING AND MAINTAINING A CERTIFICATE OF ONGOING PERFORMANCE;**

10 **(IV) SET AN APPROPRIATE TIME PERIOD FOR THE**
11 **EXPIRATION OF A CERTIFICATE OF ONGOING PERFORMANCE; AND**

12 **(V) REQUIRE, AS A CONDITION OF THE ISSUANCE OF A**
13 **CERTIFICATE OF CONFORMANCE OR A CERTIFICATE OF ONGOING**
14 **PERFORMANCE, THAT AN ACUTE GENERAL HOSPITAL AGREE TO VOLUNTARILY**
15 **RELINQUISH ITS AUTHORITY TO PROVIDE CARDIAC SURGERY SERVICES,**
16 **PRIMARY PCI SERVICES, OR NONPRIMARY PCI SERVICES IF THE HOSPITAL**
17 **FAILS TO MEET THE APPLICABLE STANDARDS ESTABLISHED BY THE**
18 **COMMISSION.**

19 SECTION 2. AND BE IT FURTHER ENACTED, That the process established
20 by the Maryland Health Care Commission for issuing a certificate of conformance, as
21 required under § 19–120.1 of the Health – General Article, as enacted by Section 1 of
22 this Act:

23 (1) shall be similar to the process through which the Commission
24 grants an exemption from certificate of need requirements for merged asset systems;
25 and

26 (2) may not allow interested party status.

27 SECTION 3. AND BE IT FURTHER ENACTED, That, notwithstanding any
28 other provision of this Act, an acute general hospital whose research waiver for
29 nonprimary PCI services was extended by the Maryland Health Care Commission
30 under COMAR 10.24.05 and that continues to meet the requirements under COMAR
31 10.24.05 may provide nonprimary PCI services until the Commission:

32 (1) makes one of the determinations or findings provided under
33 COMAR 10.24.05.05; and

1 (2) depending on the results of the C–PORT E study and the
2 Commission’s actions taken under COMAR 10.24.05.05A(1) and B, considers the
3 hospital’s application under § 19–120.1(b) of the Health – General Article, as enacted
4 by Section 1 of this Act, for a certificate of conformance for its nonprimary PCI
5 services.

6 SECTION 4. AND BE IT FURTHER ENACTED, That this Act shall take effect
7 July 1, 2012.